Abbreviated 510 (k) Summary:

CERASORB® Plus

Date Prepared: 1 December 2011

AUG 13 2012

1. SUBMISSION INFORMATION

Name and Address of the Sponsor:	Riemser Arzneimittel AG An der Wiek 7 17493 Greifswald Germany
Contact person:	Christoph Wahl Regulatory affairs dental medical devices/ Product Group Responsible Tel.: +49 – 38351-76667 Fax: +49 – 38351-7688694 E – Mail: wahl@RIEMSER.de
Registered U. S. Agent:	James M. Clinton 5105 Fairoaks Rd. Durham, NC 27712, USA Phone: 919 – 247-0479, fax: 919 – 287-2551 E – Mail: clintonjm@earthlink.net

2. DEVICE IDENTIFICATION

Proprietary Name:	**CERASORB® Plus**
Common Name:	Bone Void Filler, Synthetic
Classification Name:	Bone Grafting Material, Synthetic
Classification:	Class II, Special Controls
Classification regulation Number:	21CFR 872.3930
Product Code:	LYC

3. PREDICATE DEVICES

CERASORB® DENTAL: PMA800035/ K051443

CERASORB® M DENTAL: K051443

4. INTENDED USE

CERASORB® Plus is recommended for:

- Defects after extirpation of bone cysts
- Augmentation of the atrophied jaw ridge
- Sinus lift or sinus base elevation respectively
- Filling alveolar defects after tooth extraction for jaw ridge support
- Filling extraction defects to create an implant site
- Filling of two or multi-walled infrabony pockets, and bifurcation and trifurcation defects
- Defects after operative removal of retained teeth or corrective osteotomes

5. DESCRIPTION OF THE DEVICE

CERASORB® Plus is a sterile, synthetic, porous and biocompatible ceramic matrix roundish and polygonal crushed shaped morsels. This modification consists of pure-phase Beta-Tricalcium Phosphate with a phase purity of $\geq$ 99% and complies with the ASTM F 1088-04. The devices, when applied to a bony defect, create a network of large, smoothly interconnected pores providing different porosities (CERASORB® Plus mixture of granules with porosity of 35% and of 65%).
CERASORB® Plus is manufactured by a validated manufacturing process which guarantees batch to batch conformity and reproducibility. Due to their synthetic nature CERASORB® Plus does not pose any risk of potential allergic reactions and are neither locally nor systemically toxic.
In contact with vital bone the CERASORB® Plus granules, morsels or granulate is reabsorbed and gradually replaced by new bone.

CERASORB® Plus is provided in double sterile packages (sterilization via gamma irradiation) and are for single-use only.

The use of Beta-Tricalcium Phosphate in vivo is well known and has been studied and evaluated in numerous animal and human studies over the years. These studies indicate overall excellent performance, biocompatibility, resorption and bone regeneration with CERASORB® derived thereof the performance of CERASORB® Plus in the areas of its intended use and have proven that the material is non-toxic, biocompatible, resorbable while in contact with vital bone over time is replaced by new bone at the defect size.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

CERASORB® Plus is are substantially equivalent to a number of currently marketed and approved/cleared bone void fillers for defects in the oral/maxillofacial and dental region, such as CERASORB® DENTAL (formally regulated as a PMA800035/ K051443) and CERASORB® M DENTAL (K051443) .

Although the manufacturing process of the material is different (Beta-Tricalcium Phosphate in different porosities and morsel sizes), the intended use, recommended indications for use, target population, anatomical site, and performance data for CERASORB® Plus and the predicate devices are essentially similar. Also, all materials are resorbable and biocompatible. In contact with vital bone any of the bone grafting materials is reabsorbed and gradually replaced by new bone.

Information provided in this submission proves the effectiveness and safety of CERASORB® Plus design.

7. STATEMENT OF TECHNOLOGICAL COMPARISON

The CERASORB® Plus modification consist of pure phase Beta-Tricalcium Phosphate ceramic material according to ASTM F 1088-04. The material is of interconnecting porosity, osteoconductive and resorbable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Riemser Arzneimittel AG
C/O Mr. James Clinton
Quality And Regulatory Consulting, Limited Liability Company
5105 Fairoaks Road
Durham, North Carolina 27712

AUG 13 2012

Re: K120152
Trade/Device Name: CERASORB® Plus
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPM
Dated: June 26, 2012
Received: July 02, 2012

Dear Mr. Clinton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

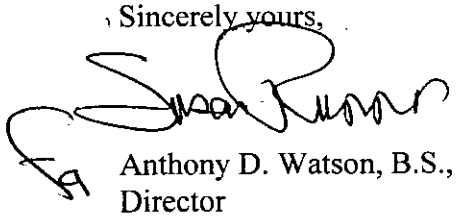
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Director of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120152

Indications for Use

510(k) Number: K120152

Device Name: CERASORB® Plus

Indications for Use:

CERASORB® Plus is recommended for:

- Defects after extirpation of bone cysts
- Augmentation of the atrophied jaw ridge
- Sinus lift or sinus base elevation respectively
- Filling alveolar defects after tooth extraction for jaw ridge support
- Filling extraction defects to create an implant site
- Filling of two or multi-walled infrabony pockets, and bifurcation and trifurcation defects
- Defects after operative removal of retained teeth or corrective osteotomes

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120152